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10/532,351	09/14/2005	Catharina Everdina Hissink	05032-00100	9053
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EXAMINER				
SU, SUSAN SHAN				
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3761				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/532,351

**Applicant(s)**

HISSINK ET AL.

**Examiner**

SUSAN SU

**Art Unit**

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 7-39 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 27-35, and 37-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1-3 and 7-39 are pending, of which claims 1, 7, & 29 are amended and Claims 8-26 and 36 are withdrawn. No new matter is added.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-5, 28, 32, 35, & 37 over Hahn have been considered but are moot because independent claims 1 & 35 have been amended to overcome the rejection.
2. Applicant's arguments filed 8 November 2010 regarding the rejection over Amsden and Grieshaber have been fully considered but they are not persuasive.

Applicant argues that as amended, the independent claims recite a "thermoplastic" polymer, which is not explicitly taught by the cited references. Applicant also cites Amsden's methods of producing the polymer to support the assertion that the polymer cannot be thermoplastic. While Examiner agrees that Amsden does not *explicitly* disclose a thermoplastic polymer, it is equally unclear if the methods employed by Amsden would necessarily result in non-thermoplastic polymers. Additionally the claim language as amended does not require that the polymer be thermoplastic *after* processing. Since the Amsden pre-polymer (e.g. [0055-0058] and Table 1, wherein the pre-polymer is a liquid, therefore it has a melting point, which makes it thermoplastic rather than thermoset) comprises the copolyester with the lactide content as claimed, Examiner asserts that it would necessarily exhibit thermoplastic properties prior to the thermal or photo crosslinking processing that may potentially change its bond structure.

Thus at least the pre-polymer taught by Amsden sufficiently meets the claim recitation of "thermoplastic polymer."

Applicant also argues that Grieshaber is directed to a drain that is designed to be permanently left inside the body. However, the Examiner asserts that it would still be obvious to one skilled in the art to modify the biodegradable material of Amsden to be made into drains shaped and sized like that taught by Grieshaber because Amsden already provides the motivation (see Abstract) that the biodegradable material can be used for a wide range of biomedical devices. Furthermore, even if the drain made from the biodegradable polymer of Amsden may not hold up permanently like it is intended for Grieshaber, employing the use of biodegradable material for the drain would allow a user the option to implant a non-permanent device shall that be the practitioner-prescribed treatment plan.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-3, 7, 27, 28, 33-35, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden (US 2003/0105245) in view of Grieshaber et al. (US 2002/0013546, "Grieshaber").

With regard to Claim 1, Amsden teaches a biocompatible, biodegradable synthetic thermoplastic polymer ([0055]-[0058] wherein the star copolymer is a plastic with a melting point, thus making it thermoplastic), the polymer has at least one softening point of at most mammalian body temperature ([0034]),

wherein the biodegradable polymer comprises at least one of a polyester ([0006]), polycarbonate, polyester-carbonate, polyanhydride, polyurethane or polyamide which are optionally combined with polyether groups, wherein the polyester that is a random DL-lactide- $\epsilon$ -caprolactone copolyester, having a lactide content of 20-75% mol% ([0083]).

Since the polyether recited in the claim is "optional," therefore Amsden need not teach the recitation.

Amsden does not teach that the polymer is part of a drain for draining human or animal antrum, organ, or tissue, but teaches that the polymer is suitable for making biomedical devices (Abstract). Grieshaber teaches a drain for draining a human antrum that is made of a biocompatible plastic. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden by applying the polymer in use for a drain such as taught by Grieshaber for the purpose of employing the polymer in useful medical applications. Although Amsden does not explicitly disclose the elastic

modulus of the polymer, but Amsden teaches the same material as recited in the claim. The discovery of a new property for a previously known composition cannot impart patentability of the known composition. When the composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are naturally expected to be present. A *prima facie* case of obviousness has been established when the combination discloses all the limitations of a claim except for an elastic modulus having specific value of less than 120MPa and the examiner cannot determine whether or not the material taught by Amsden possesses properties that render obvious the claimed invention but has a basis for shifting the burden of proof to the Applicant. The claimed elastic modulus is reasonably expected to be exhibited by the Amsden and Grieshaber combination, which has substantially the same structure and materials as claimed.

With regard to Claim 2, 28, & 33, in the combination of Claim 1, Grieshaber also teaches that the drain consists essentially of the polymer, the drain is provided with perforations, and that the drain comprises a funnel shaped element on at least one end (Fig. 5).

With regard to Claim 3, Amsden also teaches that the polymer has at least one softening point of at most 37°C ([0034]).

With regard to Claim 7, Amsden also teaches that the fraction of the L-enantiomer or the D-enantiomer of the lactide is from 65-95 mol ([0101]).

With regard to Claim 27, Amsden also teaches that the polymer is loaded with pharmaceutical components comprising peptides and proteins (Abstract).

With regard to Claims 31, 32, & 34, Amsden and Grieshaber do not teach the claimed dimensions on the drain. However, since the size of an antrum/organ varies between persons, one skilled in the art would find it obvious to optimize the length, outer diameter, funnel length and funnel diameter for better fit in the antrum or organ. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the size of Amsden and Grieshaber drain for the purpose of adapting the drain for better fit in antrums/organs other than the eye.

With regard to Claim 35, it is treated as a product-by-process claim. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product may be made by a different process. In *re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the drain as defined in Claim 1 has been shown to be the same as the combination of Amsden and Grieshaber. Although a process of production is not disclosed by the references and thus may be different from the claim, the burden shifts to the Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In *re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (US 6,669,711) in view of Amsden. Noda teaches a nasal drain (Abstract) comprising a biocompatible polymer (Col. 8 lines 63-67). Noda does not teach that the polymer is biodegradable or that it comprises at least one of the recited types of materials.

Amsden teaches a thermoplastic biodegradable polymer ([0055]-[0058] wherein the star copolymer is a plastic with a melting point, thus making it thermoplastic), the polymer has at least one softening point of at most mammalian body temperature ([0034]),

wherein the biodegradable polymer comprises at least one of a polyester ([0006]), polycarbonate, polyester-carbonate, polyanhydride, polyurethane or polyamide which are optionally combined with polyether groups, wherein the polyester that is a random DL-lactide-ε-caprolactone copolyester, having a lactide content of 20-75% mol% ([0083]).

Since the polyether recited in the claim is "optional," therefore Amsden need not teach the recitation.

Neither Noda nor discloses the elastic modulus of the polymer, but Amsden teaches the same material as recited in the claim. The discovery of a new property for a previously known composition cannot impart patentability of the known composition. When the composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are naturally expected to be present. A *prima facie* case of obviousness has been established when the combination discloses all the limitations of a claim except for an elastic modulus having specific value of less than 120MPa and the examiner cannot determine whether or not the material taught by Amsden possesses properties that render obvious the claimed invention but has a basis for shifting the burden of proof to the Applicant. The claimed elastic modulus is reasonably expected to be exhibited by the Noda and Amsden and combination, which has substantially the same structure and materials as claimed.



It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Noda with Amsden's material for the purpose of allowing for a slightly prolonged use of the drain in place without needing to remove and reinsert the drain.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden and Grieshaber as applied to claim 1 above, and further in view of Noda (US 6,669,711). Amsden and Grieshaber do not explicitly teach that the drain is a nasal drain or that the wall thickness is 0.05-5mm. Noda teaches a nasal drain made of polymeric material. Grieshaber teaches a wall thickness of 0.02mm ([0063]) for the drain that is used in the eye's Schlemm's canal. Since the nasal passage is larger than the Schlemm's canal, one skilled in the art would find it obvious to optimize the size of the drain so that it fits snugly in the antrum, and correspondingly optimize the wall thickness of the drain to maintain its structural integrity and maneuverability. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden and Grieshaber with Noda for the purpose of adapting the drain for more medical uses.

8. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden and Grieshaber as applied to claim 1 above, and further in view of Bays et al. (US 4,650,488, "Bays"). Amsden does not teach a method for treating a disorder of the body. Grieshaber teaches treating a disorder by introducing the drain into an organ (eye) such that the organ is connected with another location within the body, but Grieshaber does not explicitly teach allowing the drain to degrade over time. Bays

teaches attaching a bioabsorbable implant for ventilating the middle ear to prevent infection, thus allowing the implant to degrade over time and the degradation product of said drain be absorbed by the body. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden and Grieshaber with the application of Bays for the purpose of making more uses of the polymer.

9. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amsden, Grieshaber, and Bays as applied to claim 37 above, and further in view of Marten et al. (US 5,017,188, "Marten"). Amsden, Grieshaber, and Bays do not explicitly teach using an attachment of sealant, suture, or staple for the drain. Martens teaches using suture for securing a tubular implant in the body (Col. 6 lines 3-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Amsden, Grieshaber, and Bays with the teachings of Martens for the purpose of better securing the drain in place.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Murdoch, Dunn, Norton, and Jurgens each teaches a thermoplastic polymer formed of polylactide and epsilon-caprolactone.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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